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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,360	09/15/2003	Jian-yun Dong	22488-756	1654
7590 Dr. Benjamin Adler Adler & Associates 8011 Candle Lane Houston, TX 77071	03/22/2007		EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT 1648	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	03/22/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/663,360	DONG, JIAN-YUN	
	Examiner Louise Humphrey, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 December 2006.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-61 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-61 is/are rejected.  
 7) Claim(s) 38 and 40 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 12/15/03.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The Office acknowledges the receipt of Applicant's election filed on 19 December 2006.

### **37 CFR 1.126**

The numbering of claims is not in accordance with 37 CFR 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

In the instant application, there are two sets of claims 52-54. Misnumbered claims 52-58 have been renumbered as claims 55-61.

Reference to claim numbers within this Action is in accordance with the claim numbers as they have been renumbered.

### ***Election/Restriction***

Upon further consideration of the invention, Examiner has withdrawn the requirement for the Species Election.

Claims 1-61 are pending and examined.

### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, filed on 15 December 2003, is attached to the instant Office action.

### ***Claim Objections***

Claims 38 and 40 are objected to because of the following informalities:

Claim 38 contains the phrase "consisting of" twice.

Claim 40 contains word "tittering," which should be replaced with "counting" or "determining" because "tittering" means a nervous giggle according to the dictionary.

Appropriate correction is required.

### ***Double patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 8-12, 15, 18, 33 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 61-66 of U.S.

Patent No. 6,900,010 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations in the patented claims appear to be the same as in the instant claims. Therefore, the instant claims are anticipated by the patented claims of US 6,900,010 B2.

Claims 1-18, 24, 33, 34, 37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9-24, and 26-28 of U.S. Patent No. 6,884,576 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations in the patented claims appear to be the same as in the instant claims. Therefore, the instant claims are anticipated by the patented claims of US 6,884,576 B2.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> ¶***

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-61 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 44 lack clarity because the claim language does not point out the salient characteristics of the expression constructs inside the recombinant cells, i.e. the promoter and the heterologous insert. The definition of "productive infection" as recited in claim 1 is confusing because non-infected cells can mean non-HIV-infected or non-

virally-infected. Claim 1 also recites a "first sample" of HIV but is missing the essential element of a second or third sample.

Claims 1, 41 and 44 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps and elements, such omission amounting to a gap between the steps. See MPEP § 2172.01. There is no resolution from the final method step, such as a "wherein" clause, that ties in with the preamble of the claimed invention, *i.e.* it is unclear to one skilled in the art how detecting a change in the expression level of a reporter gene correlates with drug resistance of HIV in a sample. Furthermore, there is no method step for measuring the expression level of the reporter gene. Which reference is compared to for the change in expression level? What is the control or the reference HIV for determining the drug resistance of a HIV in a sample? Claim 41 is also missing the essential element and conditions for propagation of sample HIV.

Claims 2-43 and 45-61 are rejected for depending on indefinite base claims.

Claims 56 and 58-60, as renumbered, lack antecedent basis.

Regarding claim 18, the phrase "capable of" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Clarification and/or correction are required.

***Allowable Subject Matter***

Claims 1 and 44 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §112, 2nd paragraph, set forth in this Office action.

Claims 2-43 and 45-61 would be allowable if rewritten to overcome the rejections under 35 U.S.C. §112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: claims 1-61 are free of prior art of record. The Examiner is not aware of any suggestion in the prior art of record that would point the artisan to the claimed method for detecting drug resistance of HIV in a sample.

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***Correspondence***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.  
Primary Examiner  
10 March 2007

*L. Humphrey*  
Louise Humphrey, Ph.D.  
Assistant Examiner